

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



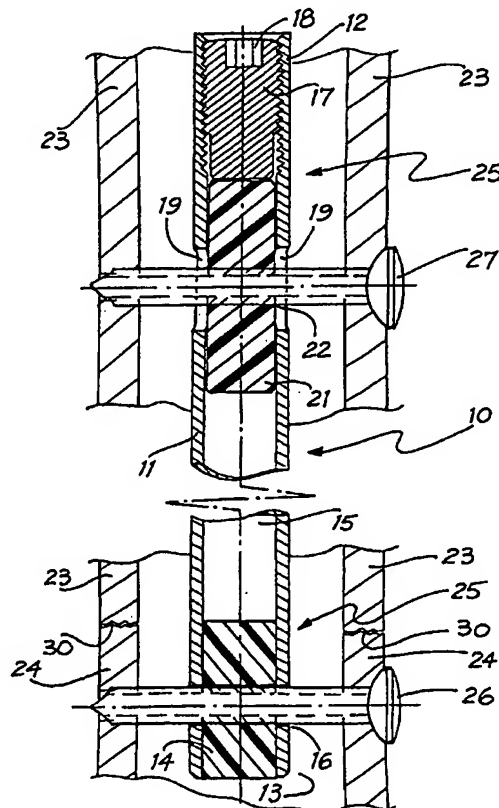
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/72		A1	(11) International Publication Number: WO 96/35387
			(43) International Publication Date: 14 November 1996 (14.11.96)
(21) International Application Number: PCT/AU96/00285		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 9 May 1996 (09.05.96)		<p>Published With international search report.</p>	
(30) Priority Data: PN 2893 9 May 1995 (09.05.95) AU			
(71) Applicant (for all designated States except US): THE UNIVERSITY OF WESTERN AUSTRALIA [AU/AU]; Perth, W.A. 6907 (AU).			
(72) Inventors; and (75) Inventors/Applicants (for US only): WOOD, David, John [GB/AU]; 38 Berkeley Crescent, Floreat, W.A. 6014 (AU). COLLOPY, Dermot, Michael [AU/AU]; 58 Alderbury Street, Floreat Park, W.A. 6014 (AU). DAY, Robert, Edward [AU/AU]; 21 May Street, East Fremantle, W.A. 6158 (AU). GUY, David, Thomas [AU/AU]; 1 Jasmin Court, Maida Vale, W.A. 6057 (AU). SCULL, Edward, Royston [AU/AU]; 1 Woodroyd Street, Mt. Lawley, W.A. 6050 (AU).			
(74) Agent: F.B. RICE & CO.; 28A Montague Street, Balmain, NSW 2041 (AU).			

(54) Title: INTRAMEDULLARY BONE NAIL

(57) Abstract

An intramedullary bone prosthesis is described that can provide for the compression of adjacent bone pieces. The bone prosthesis can comprise a nail (10) disposed within the medullary canal (25) of a long bone. The nail (10) is affixed at one end (13) by a bone screw (26) to a bone piece (24). The nail (10) also has a pair of slots (19) which can receive a bone screw (27). The bone screw (27) passes through a bone piece (23) and is disposed in a block (21) of low friction material that is movable relative to the nail (10). A threaded plug (17) which abuts the block (21) can move relative to the nail (10) and so also move the block (21) and screw (27) to cause compression of bone pieces (23, 24). A surgical procedure for the compression for two adjacent bone pieces using the nail (10) is also described.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

WO 96/35387

PCT/AU96/00285

1

Intramedullary bone nailField of the Invention

The present invention relates to an intramedullary bone prosthesis and more particularly to an intramedullary bone nail that allows the
5 compression of adjacent bone pieces.

Background Art

It is known to insert a bone nail into the intramedullary canal of a long bone for the purpose of approximating and holding adjacent bone pieces. The bone pieces may be adjacent pieces of a fractured bone or
10 adjacent pieces of endogenous bone and a bone graft. Such bone nails typically comprise an elongate tubular body which may be inserted into the intramedullary canal and two or more screws, pins or the like that connect each of the adjacent bone pieces to the tubular body of the bone nail.

Disclosure of the Invention

15 A problem with conventional intramedullary nails is that the "play" in the placement of the screw in the holes in the nail is such that it is difficult, if not impossible, to ensure that the bone pieces are urged into contact. The present inventors have devised a mechanism enabling an intramedullary nail, or like prosthesis, to hold adjacent bone pieces in
20 appropriate approximation and also in compression.

The present invention consists in an intramedullary bone prosthesis including an elongate tubular body having a longitudinal axis, an elongate slot extending through the tubular body transversely of the longitudinal axis, which slot can receive a bone engagement means extending transversely of
25 the tubular body, and displacement means disposed within the tubular body to move the bone engagement means, extending through the slot, axially of the tubular body.

In a further aspect, the present invention consists in a surgical procedure for the compression of two adjacent pieces in a long bone
30 comprising affixing one end of an intramedullary bone prosthesis according to this invention in contact with a first of the bone pieces, passing a bone engagement means through an elongate slot formed in the tubular body adjacent the other end of the intramedullary prosthesis and causing the displacement means in the tubular body to move the bone engagement
35 means towards the one end of the intramedullary prosthesis and to cause the bone pieces to be urged into contact with one another.

WO 96/35387

PCT/AU96/00285

2

The prosthesis and method according to this invention allows appropriate approximation of fracture fragments. Preferred embodiments will allow improved fracture union through the application of compression across the fracture site. These preferred embodiments will also improve the union in allograft surgery by improving the surface contact at the host-allograft interface. The application of such compression will increase the friction at the host-allograft interface and decrease the relative motion at that interface. This will increase the likelihood of union and decrease implant failure. The compression applied to the bone pieces may be maintained by leaving the prosthesis in-situ.

The intramedullary prosthesis is typically an intramedullary nail used for the approximation and compression of adjacent pieces of bone in a long bone. The adjacent pieces may be of endogenous bone or one may be endogenous bone and the other an allograft. In this situation a second bone engagement means, such as a screw, nail or the like, extending through a near size hole adjacent one end of the prosthesis, connects that end of the prosthesis to one of the bone pieces. A first bone engagement means, such as a screw, nail or the like, extends through a slot adjacent the other end of the prosthesis into the second piece of bone. The displacement means can then be adjusted to bring the bone pieces into apposition.

The intramedullary bone prosthesis may alternatively be a prosthesis having a function additional to the mere approximation of bone pieces. The prosthesis could be, for instance, a total hip replacement prosthesis or an arthrodesis prosthesis. In each case the one end of the prosthesis may be abutted against the end of a long bone, or an allograft annexed thereto, and the other end connected to the long bone by a bone engagement means, such as a screw, extending through a slot in a tubular body adjacent the other end of the prosthesis. In this case, the displacement means may be used to draw the prosthesis itself into contact with the bone or, alternatively the prosthesis may serve to draw an allograft into contact with the bone.

In a preferred embodiment of the invention the displacement means comprises an externally threaded plug disposed in the end of the tubular body which in turn is provided with a corresponding internal thread. The plug is adapted to, directly or indirectly, contact the bone engagement means extending through the slot. Rotation of the plug relative to the tubular body will cause the bone engagement means to move relative to the prosthesis.

WO 96/35387

PCT/AU96/00285

3

While the use of a threaded plug is the simplest arrangement of displacement means other suitable arrangements could be used. A cam mechanism could be used which could be approached for adjustment transversely of the prosthesis rather than the axial approach required with the plug. It would also be possible to provide remotely actuable means such as a motor disposed within the lumen of the tube that could be actuated by remote control to adjust the force on the bone engagement means, such as a screw, nail or the like, disposed in the slot from time to time rather than just at the time of the placement of the prosthesis.

10 In order to reduce the friction between the plug and the bone engagement means, which would both typically be formed of stainless steel, it is preferable to provide a low friction pad between them. This pad may comprise a simple disk of a low friction material, such as a synthetic plastics material, disposed between the plug and the bone engagement means. In an alternative arrangement, there may be a block of a suitable material, such as a synthetic plastics, slidably disposed within the lumen of the tubular body. The bone engagement means may be positioned in a near size hole in this block when it is extended through the slot. In this arrangement both the block and the bone engagement means are moved relative to the tubular body by actuation of the displacement means.

20 In those cases in which a bone engagement means, such as a screw, pin or the like, is used to connect the end of the prosthesis distal to the slot to a bone piece it may be desirable to position a suitable plug within the lumen of the tubular body. This plug may be of a suitable synthetic plastics material. The plug will either be provided with a near size hole to receive the screw, pin or the like or may be sufficiently soft that a screw, pin or the like may be driven through it. In this case the plug may be immovably disposed in the lumen of the tubular body.

30 When placing a prosthesis according to this invention the procedure is essentially similar to the procedure conventionally used for a similar, but non-compressive, prosthesis. When drilling the hole for the screw, pin or the like that is to extend through the slot the drilling jig should be set up to drill the hole so that it extends through the slot proximal to the end of the slot adjacent the displacement means. This then allows the maximum amount of travel for the screw, pin or the like relative to the prosthesis. In the case that the displacement means comprises a threaded plug in one end

WO 96/35387

PCT/AU96/00285

4

of the tubular body of the prosthesis, adjustment of the position of the screw, pin or the like in the slot relative to the prosthesis, and thus the compressive force between the adjacent bone pieces is activated by inserting a tool down the medullary canal of the long bone and rotating the plug relative to the prosthesis. The tool is inserted into the medullary canal through the aperture made to insert the prosthesis therein.

Brief Description of the Drawings

Hereinafter described by way of example only, a preferred embodiment of the present invention is described with reference to the accompanying drawings, in which:

Fig. 1 shows diagrammatically a longitudinal section through an intramedullary nail according to the present invention; and

Fig. 2 shows an end view of the intramedullary nail of Fig. 1.

Best Mode of Carrying out the Invention

The intramedullary nail 10 is formed of stainless steel or a similar inert metal and comprises a tubular body 11 having a proximal end 12 and a distal end 13. Adjacent the distal end 13 a block 14 of an ultra high molecular weight polyethylene (UHMWPE) is disposed within the lumen 15 of the tubular body 11. A transverse hole 16 extends through the tubular body 11 and the block 14 adjacent the distal end 13 of the tubular body 11. The hole 16 is sized to be just sufficient to receive a suitably sized bone screw 26. The inside surface of the proximal end 12 of the tubular body 11 is threaded and a stainless steel plug 17 having a complementary thread on its outer surface is disposed within the lumen 15 at the end 12 of the tubular body 11. The proximal end of the plug 17 is formed with a hexagonal recess 18 to receive a suitable tool to cause rotation of the plug 17 within the tubular body 11.

The tubular body 11 is formed on the distal side of the plug 17 with a pair of slots 19 on diametrically opposed sides to allow the insertion therethrough, in sliding arrangement, of a suitable bone screw 27. A block 21 of UHMWPE is slidably disposed in the lumen 15 of the tubular body 11 and has a diametric near-size hole 22 to receive the bone screw 27 extending through the slots 19. The block 21 is adapted to bear against the distal end of plug 17.

In use the intramedullary nail 10 is used to hold two pieces 23 and 24 of a fractured bone about a fracture site 30 in apposition under a

WO 96/35387

PCT/AU96/00285

5

compressive force. The nail 10 is disposed within the medullary canal 25 of the bone through an aperture (not shown) formed surgically in one or other end of the bone. A jig (not shown) is used to guide a suitable drill to drill a hole through the bone piece 24 and, if it has not already been formed,
5 through the block 14. A bone screw 26 is then inserted through the hole to connect the distal end 13 of the intramedullary nail 10 with the bone piece 24.

The jig is then used to guide a suitable drill to drill a hole through bone piece 23, slots 19 and, if required, block 21 to receive bone screw 27.
10 The hole is drilled to extend through the proximal end of the slots 19. This screw 27 serves to slidably connect the bone piece 23 to the intramedullary nail 10.

The plug 17 may then be rotated, using a suitable tool inserted into hexagonal recess 18, relative to the tubular body 11 to screw the plug 17
15 towards the distal end 13. This forces the block 21, and screw 27, distally and applies a compressive force between bone pieces 23 and 24.

While this embodiment has been described using only a single screw at each end of the intramedullary nail it will be appreciated that two or more screws could be used at each end of the nail.

20 It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

WO 96/35387

PCT/AU96/00285

6

CLAIMS:

1. An intramedullary bone prosthesis including an elongate tubular body having a longitudinal axis, an elongate slot extending through the tubular body transversely of the longitudinal axis, which slot can receive a
5 bone engagement means extending transversely of the tubular body, and displacement means disposed within the tubular body to move the bone engagement means, extending through the slot, axially of the tubular body.
2. The intramedullary bone prosthesis of claim 1 wherein the prosthesis is an intramedullary nail.
- 10 3. The intramedullary bone prosthesis of claim 1 wherein a hole extends transversely through the tubular body distal the slot, which hole can receive a second bone engagement means extending transversely of the tubular body.
4. The intramedullary bone prosthesis of claim 3 wherein the hole is
15 disposed adjacent a first end of the bone prosthesis.
5. The intramedullary bone prosthesis of claim 1 wherein the displacement means comprises a plug disposed in a second end of the tubular body and relatively moveable thereto.
6. The intramedullary bone prosthesis of claim 5 wherein the plug has
20 an external thread complementary to an internal thread on the tubular body.
7. The intramedullary bone prosthesis of claim 5 wherein the plug can contact the bone engagement means extending through the slot to so move the bone engagement means relative to the prosthesis.
8. The intramedullary bone prosthesis of claim 5 wherein a pad of low
25 friction material is disposed in the tubular body between the plug and the bone engagement means.
9. The intramedullary bone prosthesis of claim 5 wherein a block of low friction material is disposed in the tubular body between the plug and the bone engagement means.
- 30 10. The intramedullary bone prosthesis of claim 5 wherein the bone engagement means is disposed in a block of low friction material and the plug can contact the block to so move the bone engagement means relative to the prosthesis.
11. The intramedullary bone prosthesis of any one of claims 8-10
35 wherein the low friction material is ultra high molecular weight polyethylene (UHMWPE).

WO 96/35387

PCT/AU96/00285

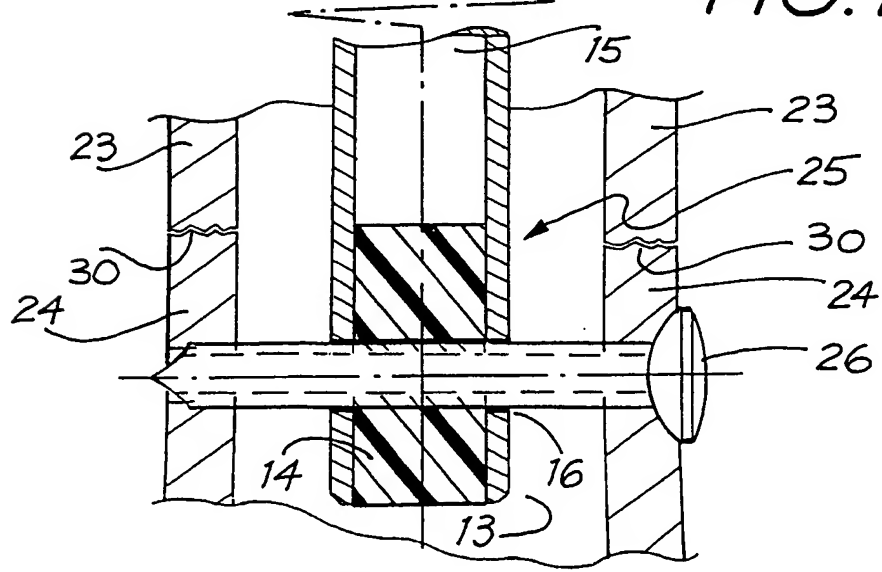
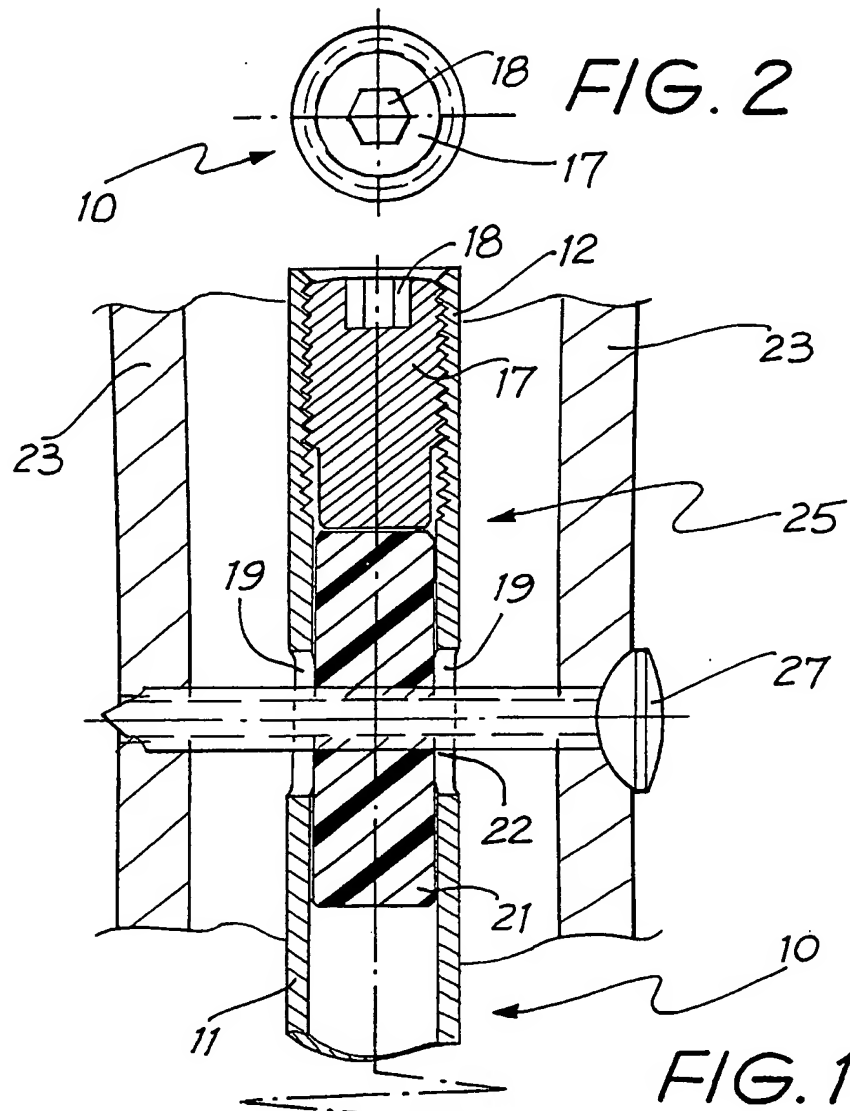
7

12. The intramedullary bone prosthesis of claim 3 wherein a plug is disposed in the tubular body proximate the hole such that the second bone engagement means passes therethrough.
13. The intramedullary bone prosthesis of claim 12 wherein the plug
5 disposed proximate the hole is ultra high molecular weight polyethylene (UHMWPE).
14. The intramedullary bone prosthesis of claim 1 wherein the bone engagement means is a screw, pin or the like.
15. The intramedullary bone prosthesis of claim 3 wherein the second
10 bone engagement means is a screw, pin or the like.
16. A surgical procedure for the compression of two adjacent pieces in a long bone comprising affixing one end of an intramedullary bone prosthesis as defined in any one of claims 1-15 in contact with a first of the bone pieces, passing a bone engagement means through a second of the bone
15 pieces and an elongate slot formed in the tubular body adjacent the other end of the intramedullary prosthesis, and causing the displacement means to move the bone engagement means towards the one end of the intramedullary prosthesis and to so relatively move the second bone piece toward the first bone piece and cause the bone pieces to be urged into contact with one
20 another.
17. The surgical procedure of claim 16 wherein the step of affixing the one end of the intramedullary bone prosthesis in contact with the first bone piece comprises passing the second bone engagement means through the first bone piece and a hole formed in the tubular body adjacent the one end.

WO 96/35387

PCT/AU96/00285

1/1



INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00285

A. CLASSIFICATION OF SUBJECT MATTER		
Int Cl ⁶ : A61B 17/72		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC A61F 1/00, 2/28, A61B 17/18, 17/56, 17/58, 17/72		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT JAPIO		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 40969/85 A (PAPAGIANNOPOULOS) 17 October 1985 Pages 2-4, figure 1	
A	US 4502160 A (MOORE et al) 5 March 1985 Whole document	
A	GB 2209947 A (HALDER et al) 1 June 1989 Figure 10	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
Date of the actual completion of the international search 1 July 1996		Date of mailing of the international search report 05 JUL 1996
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (06) 285 3929		Authorized officer S. THOMAS Telephone No.: (06) 283 2454

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 96/00285

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	AU 31168/93 A (ZOLI) 15 July 1993 Figures 1-4	

INTERNATIONAL SEARCH REPORT
Information on patent family membersInternational Application No.
PCT/AU 96/00285

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	4502160	CA	1215801	EP	144667
GB	2209947				
AU	31168/93	EP	551846		
AU	40969/85	EP	165666	JP	61029346
END OF ANNEX					